UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION	)	**Case No. 2:18-md-2846**
	)	**CHIEF JUDGE EDMUND A. SARGUS**
	)	**Magistrate Judge Kimberly A. Jolson**
This Document Relates to: KAREN STONE	)	**Civil Action No. _____**

COMPLAINT

Plaintiff files this Complaint pursuant to Case Management Order 2 and is to be bound by the rights, protections, and privileges and obligations of that Order. Plaintiff, Karen Stone, by and through counsel, brings this Complaint for damages against C.R. Bard, Inc. and Davol, Inc ("Defendants") and in support states the following:

NATURE OF ACTION

1. This products liability action is brought on behalf of the above-named Plaintiff, arising out of the failure of Defendants' hernia mesh product, the Bard® Mesh Monofilament Polypropylene Mesh ("Bard Mesh Hernia Patch"). As a result, Plaintiff suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which she may be legally entitled.

JURISDICTION AND VENUE

2. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000, exclusive of interest and costs.

3. Plaintiff is filing this Complaint as permitted by Case Management Order 2 issued by Judge Edmund A. Sargus of this Court. Plaintiff states that but for that Order permitting direct

filing into the Southern District of Ohio, Plaintiff would have filed in the United States District Court in California. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the United States District Court in California as set forth in Case Management Order 2.

4. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2846 as Plaintiff's claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of California and the State of Ohio, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of California and the State of Ohio unrelated to Plaintiff's claims.

FACTS COMMON TO ALL COUNTS

5. Plaintiff Karen Stone is a citizen and resident of Sacramento County, California and the United States.

6. Defendant Davol Inc. ("Davol") is a corporation that is incorporated under the laws of the State of Delaware. Davol has its principal place of business in the State of Rhode Island. It manufactures the Bard Mesh Hernia Patch and is located at 100 Crossings Boulevard, Warwick, Rhode Island. Davol focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy.

7. Defendant C. R. Bard Inc. ("Bard") is a corporation that is incorporated under the laws of the State of New Jersey. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the Bard Mesh Hernia Patch. It also manufactures and supplies Davol with material that forms part of the Bard Mesh Hernia Patch.

8. Upon information and belief, at all relevant times, Defendants transacted, solicited, and conducted business in the State of Rhode Island, New Jersey, California and Ohio and derived

substantial revenue from such business.

9. The Bard Mesh Hernia Patch was designed and is manufactured and distributed by Defendants who own the patent on the device that was inserted into Plaintiff's body.

10. Defendants designed, manufactured and distributed the Bard Mesh Hernia Patch that was inserted into Plaintiff's body.

11. Defendants, through its agents, servants, and employees, participated in the manufacture and delivery of the Bard Mesh Hernia Patch that was inserted into Plaintiff's body.

12. The Bard Mesh Hernia Patch product implanted in Plaintiff was designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair surgeries and was further represented by Defendants to be an appropriate, cost-effective and suitable product for such purpose.

13. Plaintiff was never informed by Defendants of the defective, dangerous nature of the Bard Mesh Hernia Patch.

14. Neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of the Bard Mesh Hernia Patch or that this unreasonably defective condition was the cause of Plaintiff's injuries.

15. Upon information and belief Defendants failed to comply with the FDA application and reporting requirements.

16. Upon information and belief Defendants were aware of the high degree of complication and failure rate associated with their Bard Mesh Hernia Patch.

17. Upon information and belief Defendants were aware of the defect in manufacture and design of their Bard Mesh Hernia Patch.

18. The Bard Mesh Hernia Patch is designed, indicated, and utilized for permanent

implantation in the human body.

19. Upon information and belief, Defendants failed to warn or notify doctors, regulatory agencies, and/or consumers of the severe and life-threatening risks associated with their Bard Mesh Hernia Patch.

20. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the Bard Mesh Hernia Patch.

21. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the Bard Mesh Hernia Patch but did not readily disclose this information.

22. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

23. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

24. Defendants marketed the Bard Mesh Hernia Patch to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products.

25. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Bard Mesh Hernia Patch.

26. Defendants' Bard Mesh Hernia Patch product contains polypropylene. Despite Defendants' claims that this material is inert, a substantial body of scientific evidence shows that the mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving the product. This immune response promotes

degradation and contracture of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

27. Upon information and belief, Defendants' numerous suppliers of various forms of polypropylene cautioned all users in their United States Material Safety Data Sheet that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

28. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

29. Defendants failed to design and establish a safe, effective procedure for removal of the Bard Mesh Hernia Patch; therefore, in the event of a failure, injury, or complications it is difficult to safely remove the Bard Mesh Hernia Patch.

30. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Bard Mesh Hernia Patch, including providing the warnings and instructions concerning the product.

31. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the Bard Mesh Hernia Patch for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including Plaintiff.

32. The Bard Mesh Hernia Patch was utilized and implanted in a manner foreseeable to Defendants.

33. The Bard Mesh Hernia Patch was implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

34. On or about November 25, 2016, Plaintiff underwent surgery for repair of a ventral hernia. A Bard Mesh Hernia Patch, Reference number 0112720 was implanted into Plaintiff's body to repair the hernia defect.

35. At the time of the operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with the Bard Mesh Hernia Patch.

36. Plaintiff was never informed by Defendants of the defective and dangerous nature of the Bard Mesh Hernia Patch.

37. At the time of the implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of the Bard Mesh Hernia Patch.

38. On or about January 9, 2017, Plaintiff underwent an invasive surgical procedure to remove the Bard Mesh Hernia Patch.

39. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

40. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

41. Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, which include intentional concealment from Plaintiff and/or the general public that the Bard Mesh Hernia Patch is defective, while continually marketing the product with the effects described in this Complaint.

42. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiff could not reasonably have known Bard Mesh Hernia

Patch was defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

43. Despite diligent investigation by Plaintiff into the cause of Plaintiff's injuries, including consultations with her medical providers, the nature of the injuries and damages, and their relationship to the Bard Mesh Hernia Patch was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

44. Plaintiff did not learn of Defendants' wrongful conduct until after January 9, 2017. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

45. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

46. Defendants expected and intended the Bard Mesh Hernia Patch to reach users such as Plaintiff in the condition in which the product was sold.

47. The implantation of the Bard Mesh Hernia Patch in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

48. When the Bard Mesh Hernia Patch was implanted in Plaintiff's body it was defectively manufactured.

49. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Bard Mesh Hernia Patch implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

50. Upon information and belief, Defendants utilized substandard and adulterated raw materials used to make the Bard Mesh Hernia Patch, which deviated from Defendants' material and supply specifications.

51. The Bard Mesh Hernia Patch failed to perform safely and effectively for the purpose it was originally designed. Plaintiff's device failed while in her body causing her to develop serious physical complications which required subsequent, painful and unnecessary surgery as a result of her Bard Mesh Hernia Patch.

52. As a direct and proximate result of the defective manufacture of the Bard Mesh Hernia Patch, Plaintiff suffered injuries and damages as summarized in this Complaint.

53. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

54. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

55. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

56. The Bard Mesh Hernia Patch was defectively designed and/or manufactured and was not reasonably safe for its intended use in hernia repair; and the risks of the design outweighed any potential benefits associated with it. As a result of the defective design and/or manufacture of the Bard Mesh Hernia Patch, there was an unreasonable risk of severe adverse reactions to the mesh or its components including: chronic infections; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications.

57. When affixed to the body's tissue, the Bard Mesh Hernia Patch prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

58. The Bard Mesh Hernia Patch is defective in its design and is unreasonably dangerous to Plaintiff.

59. The Bard Mesh Hernia Patch is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

60. These manufacturing and design defects associated with the product were directly and proximately related to the injuries Plaintiff suffered.

61. Neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of the product. Moreover, neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the risks associated with the Bard Mesh Hernia Patch.

62. The product implanted in Plaintiff failed to reasonably perform as intended. It caused serious injury and had to be removed via invasive surgery and necessitated additional invasive surgery to repair the hernia that the product was initially implanted to treat.

63. When the Bard Mesh Hernia Patch was implanted in Plaintiff's body, it was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning the product's risks.

64. Defendants expected and intended the product to reach users such as Plaintiff in the condition in which the product was sold.

65. The implantation of the Bard Mesh Hernia Patch in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

66. The risks of the product significantly outweigh any benefits that Defendants contend could be associated with it. The Bard Mesh Hernia Patch incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection.

67. The Bard Mesh Hernia Patch was in itself dangerous and defective, particularly when used in the manner intended by Defendants. The material used in the Bard Mesh Hernia Patch was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. When implanted adjacent to internal organs, as Defendants intended for the Bard Mesh Hernia Patch, the mesh is unreasonably susceptible to adhesion, perforation or erosion, fistula

formation, hernia incarceration, and other injuries.

68. The appropriate treatment for complications associated with the Bard Mesh Hernia Patch involves additional invasive surgery in an attempt to remove the mesh from the body, thus eliminating any purported benefit that the product was intended to provide to the patient.

69. When the Bard Mesh Hernia Patch was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products available.

70. The Bard Mesh Hernia Patch product provides no benefit to consumers over other mesh types and increased the risks to patients implanted with these devices.

71. The Bard Mesh Hernia Patch product implanted in Plaintiff failed to reasonably perform as intended and had to be surgically removed. Thus, further invasive surgery was necessary to repair the very problem that the product was intended to repair, providing only harm and no benefit to him.

72. As a direct and proximate result of the defective and unreasonably dangerous condition of the Bard Mesh Hernia Patch, Plaintiff suffered injuries and damages.

73. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

74. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

75. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

76. When the Bard Mesh Hernia Patch was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the product were inadequate and defective. There was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

77. Defendants expected and intended the product to reach users such as Plaintiff in the condition in which it was sold.

78. Plaintiff and/or Plaintiff's physicians were unaware of the defects and dangers of the Bard Mesh Hernia Patch, and were unaware of the frequency, severity and duration of the risks associated with the product.

79. Defendants' Instructions for Use provided with the product expressly understate and misstate the risks known to be associated specifically with it. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Bard Mesh Hernia Patch.

80. Defendants' Instructions for Use failed to adequately warn Plaintiff's physicians of numerous risks, which Defendants knew or should have known were associated with the Bard Mesh Hernia Patch, including the following: immunologic response, infection, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, obstruction, and tumor or cancer formation.

81. Defendants' Instructions for Use also failed to instruct physicians how much larger than the hernia defect the product needed to be for an effective repair.

82. As well, the Instructions for Use failed to disclose the extent the Bard Mesh Hernia Patch would shrink, or that it would even shrink at all.

83. Defendants failed to adequately warn Plaintiff and/or her physicians about the need for invasive surgical intervention in the event of complications or inform them of the treatment for such complications when they occurred.

84. Defendants failed to adequately warn Plaintiff and/or her physicians that the surgical removal of the Bard Mesh Hernia Patch, in the event of complications, would leave the hernia unrepaired and the resulting hernia would be much larger than the original. Thus, more complicated medical treatment would be needed to attempt to repair the same hernia that the failed product was intended to treat.

85. Defendants failed to adequately warn Plaintiff and/or her physicians that in the event of complications, the product is more difficult to fully remove than other feasible hernia meshes that have been available at all material times.

86. Defendants failed to warn Plaintiff and/or her physicians that as a result of being implanted with the Bard Mesh Hernia Patch, she would be at a higher risk of infection and/or other complications for the remainder of her life.

87. With respect to the complications listed in Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with the Bard Mesh Hernia Patch were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

88. If Plaintiff and/or her physicians had been properly warned of the defects and dangers of the Bard Mesh Hernia Patch, and of the frequency, severity and duration of the risks associated with the product, she would not have consented to allow the product to be implanted, and her physicians would not have implanted it.

89. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

90. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

91. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT IV: NEGLIGENCE

92. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

93. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Bard Mesh Hernia Patch, but failed to do so.

94. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, creating, and/or designing the Bard Mesh Hernia Patch without thoroughly testing it;

(b) Manufacturing, producing, promoting, creating, and/or designing the Bard Mesh Hernia Patch without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not the Bard Mesh Hernia Patch was safe for use and/or implantation; in that Defendants herein knew or should have known that the Bard Mesh Hernia Patch was unsafe and unfit for use and/or implantation by reason of the dangers to its users;

(d) Selling the Bard Mesh Hernia Patch without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, and/or the medical and healthcare profession, and the FDA of the dangers of the Bard Mesh Hernia Patch;

(f) Negligently advertising and recommending the use of the Bard Mesh Hernia Patch without sufficient knowledge as to its dangerous and harmful properties;

(g) Negligently representing that the Bard Mesh Hernia Patch was safe for use for its intended purpose, when, in fact, it was unsafe and harmful;

(h) Negligently representing that the Bard Mesh Hernia Patch had equivalent safety and efficacy as other types of mesh products used in similar hernia repairs;

(i) Negligently designing the Bard Mesh Hernia Patch in a manner which was dangerous to its users;

(j) Negligently manufacturing the Bard Mesh Hernia Patch in a manner which was dangerous to its users;

(k) Negligently assembling the Bard Mesh Hernia Patch in a manner which was dangerous to its users;

(l) Concealing information from Plaintiff and/or implanting surgeons in knowing that the Bard Mesh Hernia Patch was unsafe and dangerous;

(m) Improperly concealing and/or misrepresenting information from Plaintiff and/or healthcare professionals, concerning the severity of risks and dangers of the Bard Mesh Hernia Patch compared to other hernia mesh devices used in similar hernia repairs.

95. Defendants knew, or in the exercise of reasonable care should have known, that the product was defectively and unreasonably designed and/or manufactured and was unreasonably dangerous and likely to injure patients in whom it was implanted. Defendants knew or should have known that Plaintiff and/or her physicians were unaware of the dangers and defects inherent in the product.

96. Defendants utilized non-medical grade raw materials.

97. Defendants knew or should have known that the mesh components are not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

98. Defendants knew or should have known that the Bard Mesh Hernia Patch incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

99. Defendants knew or should have known that Bard Mesh Hernia Patch incites its own chronic inflammatory response wherever it embeds.

100. Defendants knew or should have known that the Bard Mesh Hernia Patch is associated with high rates of severe chronic infections.

101. Defendants knew or should have known that Bard Mesh Hernia Patch degrades in the presence of bacteria.

102. Defendants knew or should have known that all subsequent operations carry a greater risk of infection after the patient has been implanted with a Bard Mesh Hernia Patch.

103. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Bard Mesh Hernia Patch, Plaintiff suffered injuries and damages as summarized in this Complaint.

104. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

105. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT V: BREACH OF IMPLIED WARRANTY

106. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

107. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold their Bard Mesh Hernia Patch product.

108. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff and/or her implanting physician in fact used it; and Defendants impliedly warranted that the product and its component parts was of merchantable quality, safe and fit for such use, and adequately tested.

109. Defendants were aware that consumers, including Plaintiff and/or her physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Bard Mesh Hernia Patch.

110. Defendants' Bard Mesh Hernia Patch was expected to reach, and did in fact reach consumers, including Plaintiff and/or her physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

111. Defendants breached various implied warranties with respect to the Bard Mesh Hernia Patch, including the following:

(a) Defendants represented to Plaintiff and/or her physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was safe. But at the same time, they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Bard Mesh Hernia Patch;

(b) Defendants represented to Plaintiff and/or her physicians and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But at the same time, they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

(c) Defendants represented to Plaintiff and/or her physicians and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time, they fraudulently concealed information regarding the true efficacy of the Bard Mesh Hernia Patch.

112. In reliance upon Defendants' implied warranties, Plaintiff individually, and/or by and through her physician, used the Bard Mesh Hernia Patch as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

113. Defendants breached their implied warranties to Plaintiff in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

114. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering,

severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

115. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

116. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT VI: VIOLATION OF CONSUMER PROTECTION LAWS

117. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

118. Plaintiff purchased and used the Bard Mesh Hernia Patch primarily for personal use, and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

119. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the product and would not have incurred related medical costs and injury.

120. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Bard Mesh Hernia Patch, which would not have been paid but for Defendants' unfair and deceptive conduct.

121. Unfair methods of competition or deceptive acts or practices proscribed by law include the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

122. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct, directed at patients, physicians and/or consumers, was to create demand for and sell the Bard Mesh Hernia Patch. Each aspect of Defendants' conduct combined to artificially create sales of the product.

123. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Bard Mesh Hernia Patch.

124. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the product and would not have incurred related medical costs.

125. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, and/or physicians and/or consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

126. Defendants' actions constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes.

127. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of 15 U.S.C. §§ 2301-2312 (1982), Cal Bus & Prof Code § 17000 *et seq*. and § 17500 *et seq*.; and Ohio Rev. Code § 1345, *et. seq*.

128. The statutes listed above were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

Defendants are the suppliers, manufacturers, advertisers, and sellers, subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

129. Defendants violated the statutes enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Bard Mesh Hernia Patch was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous; and by other acts alleged in this Complaint. These representations were made in marketing and promotional materials.

130. Defendants' actions and omissions are uncured or incurable deceptive acts under the consumer protection statutes.

131. Defendants had actual knowledge of the defective and dangerous conditions of the Bard Mesh Hernia Patch but failed to take any action to cure those conditions.

132. Plaintiff and/or the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

133. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and/or consumers, constituted unfair and deceptive acts and practices.

134. By reason of the unlawful acts in which Defendants engaged, and as a direct and proximate result, Plaintiff has suffered ascertainable losses and damages.

135. As a direct and proximate result of Defendants' violations of the consumer protection laws, Plaintiff has sustained economic losses and other damages, and are entitled to statutory and compensatory damages in an amount to be proven at trial.

136. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well

as mental anguish and emotional distress.

137. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT VII: GROSS NEGLIGENCE

138. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

139. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and for which Plaintiff will seek at the appropriate time, the imposition of exemplary damages. That is because Defendants' conduct, including the failure to comply with applicable federal standards was specifically intended to cause substantial injury to Plaintiff. Their conduct, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and Defendants were actually, subjectively aware of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included Defendants' false material representations, with their knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that Plaintiff would act upon their representation.

140. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

141. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time, in an amount within the jurisdictional limits of the Court.

142. Plaintiff also alleges that Defendants' acts and omissions, whether taken singularly

or in combination with others, constitute gross negligence, proximately causing their injuries. In that regard, Plaintiff will seek exemplary damages in an amount to punish Defendants for their conduct, and to deter other manufacturers from engaging in such misconduct in the future.

143. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

144. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT VIII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

145. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

146. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Bard Mesh Hernia Patch to Plaintiff.

147. Defendants carelessly and negligently concealed the harmful effects of the product from Plaintiff and/or her physician on multiple occasions and continue to do so to this day.

148. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Bard Mesh Hernia Patch to Plaintiff and/or her physician on multiple occasions and continue to do so to this day.

149. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that she sustained, and will continue to sustain, emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Bard Mesh Hernia Patch.

150. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the Bard Mesh Hernia Patch to Plaintiff and/or her physician, after she sustained emotional distress, severe physical injuries, and economic loss.

151. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the product to Plaintiff and/or her physician, knowing that doing so would cause her to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

152. As a proximate result of Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

153. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

154. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT IX: FRAUDULENT CONCEALMENT

155. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

156. At all material times Defendants knew or should have known that the Bard Mesh Hernia Patch caused large numbers of complications. Moreover, they knew or should have known that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices; the safety and efficacy of the Bard Mesh Hernia Patch had not been proven with respect to, among other things, the product, its components, its performance,

and its method of insertion; and that the product was not safe and effective. Defendants continued to represent that it was safe and effective.

157. Although Defendants knew or should have known about the lack of safety and efficacy of the Bard Mesh Hernia Patch, they failed to disclose this information to Plaintiff, and/or the treating physicians, and/or the public at large.

158. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and/or her physicians the true facts concerning the Bard Mesh Hernia Patch, i.e., its dangerous and defective nature, its lack of efficacy for its purported use and lack of safety in normal use, and its likelihood to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff was implanted with the Bard Mesh Hernia Patch.

159. Defendants were under a duty to Plaintiff to disclose and warn her of the defective nature of the product because:

(a) Defendants were in a superior position to know the product's true quality, safety, and efficacy;

(b) Defendants knowingly made false claims about the product's safety and quality in documents and marketing materials; and

(c) Defendants fraudulently and affirmatively concealed the defective nature of the product from Plaintiff.

160. The facts Defendants concealed and/or did not disclose to Plaintiff were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use the Bard Mesh Hernia Patch.

161. At all material times, Defendants willfully, intentionally, and maliciously

concealed facts from Plaintiff and/or her physician, with the intent to defraud.

162. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Bard Mesh Hernia Patch so that Plaintiff would request and purchase the product; and her healthcare providers would dispense, prescribe, and recommend the product. Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to her detriment.

163. At all material times, neither Plaintiff nor her physician were aware of the facts.

164. Had they been so aware, they would not have reasonably relied upon the representations of safety and efficacy and would not have utilized the Bard Mesh Hernia Patch. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physician's selection of the Bard Mesh Hernia Patch. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff as a patient.

165. As a direct and proximate result of this conduct, Plaintiff was injured.

166. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

167. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT X: NEGLIGENT MISREPRESENTATION

168. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

169. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and/or the public, that the Bard Mesh Hernia Patch had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were

in fact false.

170. Defendants failed to exercise ordinary care in their representations concerning the Bard Mesh Hernia Patch while involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the product, because they negligently misrepresented the product's risk of unreasonable and dangerous adverse side effects.

171. Defendants breached their duty by representing to Plaintiff and/or her physician, and/or the medical community that the Bard Mesh Hernia Patch has no serious side effects different from older generations of similar products or procedures.

172. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew, or had reason to know, that the Bard Mesh Hernia Patch had been insufficiently tested, or had not been tested at all; and that the product lacked adequate and accurate warnings, and created a high risk—and/or higher than acceptable or reported and represented risk—of adverse side effects, including pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

173. As a direct and proximate result of Defendants' conduct, Plaintiff has been injured and sustained past and future severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

174. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

175. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

PUNITIVE DAMAGES ALLEGATIONS

176. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

177. Defendants failed to adequately test and study the Bard Mesh Hernia Patch to determine and ensure that the product was safe and effective prior to releasing it for sale for permanent human implantation; and Defendants continued to manufacture and sell the product after obtaining knowledge and information that it was defective and unreasonably unsafe.

178. Defendants developed, designed and sold the product, and continue to do so, because it has a significantly higher profit margin than safer hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Bard Mesh Hernia Patch, including the risk of failure and serious injury, such as that suffered by Plaintiff.

179. At all material times, Defendants knew or should have known that the Bard Mesh Hernia Patch was inherently more dangerous with respect to the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to attempt to cure the conditions related to use of the product, as well as the other severe and personal injuries that are permanent and lasting.

180. Defendants' misrepresentations include knowingly withholding material information form the medical community and/or the public, including Plaintiff, concerning the safety and efficacy of the Bard Mesh Hernia Patch, depriving Plaintiff and/or her implanting physicians of vitally necessary information with which to make a fully informed decision about

whether to use the product.

181. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Bard Mesh Hernia Patch can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

182. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Bard Mesh Hernia Patch can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment, and recklessly failed to advise the medical community and/or the general public, including Plaintiff, of those facts.

183. At all material times, Defendants intentionally misstated and misrepresented data; and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the Bard Mesh Hernia Patch.

184. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of the Bard Mesh Hernia Patch, and its increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and/or to consumers without disclosing the true risk of such complications.

185. When Plaintiff was implanted with the Bard Mesh Hernia Patch, and since then, Defendants have known the product was defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell the product so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the Bard Mesh

Hernia Patch to members of the public, including Plaintiff.

186. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the Bard Mesh Hernia Patch, in order to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff.

187. Defendants' conduct, acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff Karen Stone demands judgment against Defendants, individually, jointly, and severally, and in the alternative, requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants, individually, jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Costs of these proceedings, including past and future costs of the suit;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

viii. Such other and further relief as this Court deems just and proper.

Dated: November 16, 2018

/s/ Michael A. London
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DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

/s/ Michael A. London
Michael A. London, Esq.